REMARKS/ARGUMENTS

Applicant responds herein to the Office Action dated March 22, 2006. A Petition for Extension of Time (three months) and the fee therefor are enclosed.

Applicant's attorneys appreciate the Examiner's thorough search and examination of the present patent application.

Claims 1-5 are pending in this application. All the claims have been rejected.

Claims 1-4 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,626,857 to Ohta et al. ("Ohta").

Claim 5 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Ohta, as applied above, in view of U.S. Patent No. 4,828,543 to Weiss et al. ("Weiss").

Reconsideration and withdrawal of these rejections are respectfully requested.

New independent claims 6 and 7 were added to better articulate characteristics of the inventive CRRT apparatus. The following distinguishing elements are recited in independent claim 6: a relatively small blood flow rate (between 280-300 ml/min); the oxygenating device disposed and acting on the blood path; and the location of the oxygenating device upstream from the haemofilter and downstream from the blood pump. These elements highlight differences between the present claimed invention and the state of the art described in the prior art references.

The claims of the present application are directed to a Continuous Renal Replacement Therapy apparatus (CRRT). The CRRT is not a dialysis apparatus or other apparatuses cited in the prior art. The speed of flow of the blood under treatment in a CRRT apparatus is about a few hundred ml/minute. This rate is relatively low with respect to the rate values of other blood treatment apparatuses.

U.S. Patent 6,349,170, cited in the specification of the present application, states in column 1, lines 62-63, that a "[t]ypical blood flow rate in CRRT is approximately 120 ml/min". The present application, on page 6, line 17, teaches, "a pump flow rate (QB) of 280-300 ml/min". Hence, the blood flow rate of the present claimed invention is greater than that of other known CRRT apparatuses, i.e., the rate of 280-300 ml/min instead of a common rate of about 120 ml/min.

In particular, in col. 18, lines 24-25 and in claim 10 Ohta describes fluid replacement rate of 10 to 800 ml/min., preferably 50 to 500 ml/min. and more preferably 100 to 400 ml/min. Further, in claim 10 Ohta identifies a flow rate of its blood filtration unit as 10 to 200 ml/min., preferably 50 to 170 ml/min., and more preferably 100 to 140 mil/min. This is far below the flow rate of 280-300 ml/min. recited in new independent claim 6 of the present application.

OXYGENATION

Another distinctive feature of the claimed CRRT apparatus, is that it acts directly on the blood flow. In accordance with the present invention, the oxygenating device is disposed in and is acting directly on the flow of the blood. As shown in Figure 1 and described on page 4, line 5 to page 5, line 2 of the specification, the blood path in the apparatus 1 is defined by the catheter 9, the conduit 90, the portions 91, 92, 93, 94, 95, and the catheter 9'. In other words, the blood passes directly through the oxygenating device 7. This feature distinguishes the inventive apparatus over the prior art and is advantageous in all cases in which the oxygen concentration of the blood requires supplementing and especially in eliminating CO_2 in patients for whom correct substitute respiration therapy is difficult to apply. Oxygenation of blood in a CRRT machine is completely new and is not taught or suggested by the prior art references.

OXYGENATING MEMBRANES

In a further distinguishing feature claim 1 recites: "an oxygenating device connected on the blood path upstream of the blood filtration means." (emphasis added). That is, the oxygenating device 7 of the present invention is located upstream of the haemofilter 8 and downstream of the blood processing means comprising the blood pump 3. This location of the oxygenating device is particularly important because it allows the oxygenating membranes of the oxygenating device to operate without the (negative) intake pressure along the portion upstream of the blood pump and without the blood concentration characteristic of the venous portion, which may eventually impair efficiency of the oxygenating membranes.

Ohta describes an extracorporeal circulation apparatus used for the selective temperature controlling method in which a temperature of an object is kept at a predetermined temperature. The Ohta's apparatus is used in anti-blastic therapies with the aim of warming or cooling in a

specific way an organ being treated. The use of the Ohta apparatus determines the so called "organ haemofiltration". This treatment is very different from that of the apparatus of the present patent application. Ohta describes an apparatus which is not a CRRT apparatus, is not provided with an oxygenating device on the blood circuit, and which has no means for feeding refill liquid into the blood.

In Fig. 1, Ohta illustrates a blood concentration/filtration/dialyzer device (13) positioned immediately upstream (not downstream) of a heat exchanger (6). Fig. 1 of Ohta shows two paths. First, a blood path that starts at catheter 11 and connects a withdrawal pump 5, a drip chamber 12, a blood concentration element 13, a heat exchanger 6, a drip chamber 16, and a bubble detector 46 and ends at catheter 15. No oxygenating devices are shown on the blood path. Second, a fluid path that starts at a fluid replacement tank (8) and connects a heat exchanger 3, a drip chamber 9, a filter 40 (selectively provided for removal of contaminants in the fluid replacement) and ends in a catheter 10.

In Fig. 2, Ohta shows an embodiment in which a third path is created to direct blood from the drip chamber 12 of the first path through an oxygenating device 28 to the heat exchanger 3 on the second path. The third path bypasses the blood filtration unit 13. Fig. 3 shows a similar path except the blood is transfusion blood (31) not from the first path. Fig. 4 simply adds the oxygenating device 28 on the second path upstream of the heat exchanger 3 without adding a blood path. Finally, Fig. 5 shows the drip chamber 9 of the second path being modified by an addition of an oxygenating device. However, the second path is a fluid path distinct from the first path, which is the blood path. Fig. 5 shows oxygenation of fluids, blood is shown to be added to the path just before the filter 40 without passing through the modified drip chamber 9.

In the present invention a blood path is created through which blood is pumped out of the patient, oxygenated, then filtered and returned to the patient. Ohta does not teach that. Thus, Ohta does not teach, describe, or suggest at least "an oxygenating device cascade-connected on the blood path upstream of the blood filtration means" recited in amended independent claim 1 and "an oxygenating device located upstream from said blood filtration means and downstream from said pump, said pump pumping the blood downstream from the connecting means to the oxygenating device at a flow rate of 280-300 ml/min." recited in new independent claim 6.

Weiss does not remedy the deficiencies of Ohta.

A declaration in Italian and its partial translation was provided by the Applicant and is enclosed herewith. The declaration is from Dr. Livigni of an Italian Medical Institute (a Turin Hospital) regarding the experimental test of the apparatus described in the present patent application. From the declaration it is evident that reduction of 20% of CO_2 in the blood is possible through treatment with the apparatus described in the present application. This value is not obtainable with the prior art apparatus. If the Examiner will deem the enclosed helpful in overcoming claim rejections an affidavit or a declaration under 37 CFR 1.132 will be submitted.

Thus, Applicants' independent claims 1 and 6 are patentably distinct from Ohta, Weiss, or their combination. Claims 2-5 and new claim 7 depend directly or indirectly from above discussed independent claims and are, therefore, patentable for the same reasons, as well as because of the combination of features in those claims with the features set forth in the respective independent claims.

Accordingly, the Examiner is respectfully requested to reconsider the application, allow the claims as amended and pass this case to issue.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on September 19, 2006:

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Respectfully submitted,

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